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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,604	12/07/2001	Pablo D. Garcia	002441.00008	6543

7590 11/21/2003

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EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/21/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,604

Applicant(s)

GARCIA ET AL.

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The claims are objected to under 37 CFR 1.71, as being so incomprehensible as to preclude a reasonable search of the prior art by the examiner. For example, the following items are not understood: "X%", "of *a* amino acids" .

Applicant is required to submit an amendment which clarifies the disclosure so that the examiner may make a proper comparison of the invention with the prior art.

Applicant should be careful not to introduce any new matter into the disclosure (i.e., matter which is not supported by the disclosure as originally filed).

Drawings

The formal drawing submitted Paper No. 10 have been reviewed and approved by the Draftsperson, see attached notice of Draftsperson review.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, drawn to a method of diagnosing prostate cancer, classified in class 435, subclass 6.
- II. Claims 16-24 and 32-34*, 38*, drawn to an isolated polynucleotide, classified in class 536, subclass 23.6.
- III. Claims 25-28, and 32-34*, 38*, drawn to an isolated polypeptide, classified in class 530, subclass 300.

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- IV. Claims 29-31 and 32-34*, 38*, drawn to antibodies directed to the polypeptide, classified in class 530, subclass 389.1.
- V. Claim 35, drawn to a method screening compounds with activity against prostate, classified in class 435, subclass 4.
- VI. Claims 36, drawn to the “use” of an inhibitor of HML-2 protease; note the “use” claim is interpreted as a method, classified in class 514, subclass 50.
- VII. Claims 37, drawn to the “use” of a transdominant negative mutant of HML-2 cORF; note the “use” claim is interpreted as a method, classified in class 435, subclass 325.

*Note claims 32-34 and 38 will be evaluated to the extent that the claims read on either the polynucleotide, polypeptide or antibody.

For invention set I above, restriction to one of the following is also required under 35 USC 121. Therefore, election is to a single sequence set forth in:

- 1 : N1-N5 [SEQ ID NO:155 - SEQ ID NO:5]
- 2: N1-N2-N5 [SEQ ID NO:155 - SEQ ID NO:156- SEQ ID NO:5]
- 3: N1-N3-N5 [SEQ ID NO:155 - SEQ ID NO:6- SEQ ID NO:5]
- 4: N1-N4-N5 [SEQ ID NO:155 – any RNA sequence- SEQ ID NO:5]
- 5: N1-N2-N3-N5 [SEQ ID NO:155 – SEQ ID NO: 156 - SEQ ID NO:6- SEQ ID NO:5]
- 6: N1-N2-N4-N5 [SEQ ID NO:155 – SEQ ID NO: 156 - any RNA sequence- SEQ ID NO:5]
- 7: N1-N3-N4-N5 [SEQ ID NO:155 –SEQ ID NO:6- any RNA sequence- SEQ ID NO:5]
- 8 : N1- N2-N3-N4-N5 [SEQ ID NO:155 –SEQ ID NO:156-SEQ ID NO: 6- any RNA sequence- SEQ ID NO:5]

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For invention sets II above, restriction to one of the following is also required under 35 USC 121. Therefore, election is to a single sequence set forth in:

SEQ ID NO: 7-39; SEQ ID No: 44; SEQ ID No:45; SEQ ID No: 59-91; SEQ ID No: 93; SEQ ID No: 95; SEQ ID No:97; SEQ ID No:99-102; SEQ ID No:105; SEQ ID No: 107; SEQ ID No: 110-145; SEQ ID No: 150-157; SEQ ID No:161-225.

For each of invention sets III and IV above, restriction to one of the following is also required under 35 USC 121. Therefore, election is to a single sequence set forth in:

SEQ ID No: 109; SEQ ID No: 146; SEQ ID No: 147; SEQ ID No:148; SEQ ID No:149

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-8 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polynucleotides. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

Inventions SEQ ID NO: 7-39; SEQ ID No: 44; SEQ ID No:45; SEQ ID No: 59-91; SEQ ID No: 93; SEQ ID No: 95; SEQ ID No:97; SEQ ID No:99-102; SEQ ID No:105; SEQ ID No: 107; SEQ ID No: 110-145; SEQ ID No: 150-157; SEQ ID No:161-225 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polynucleotides. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

Inventions SEQ ID No: 109; SEQ ID No: 146; SEQ ID No: 147; SEQ ID No:148; SEQ ID No:149 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed

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as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides. Therefore, where structural identity is required the different sequences have different effects.

Inventions I and II are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of diagnosing prostate cancer can be accomplished with antibodies, which are different products.

Groups II-IV are compositions and are distinct from groups I and V-VII which are drawn to methods. Groups II-IV are compositions and each is distinct from the other because they contain different materials. Group II comprises the DNA sequence made up of nucleic acids. Group III comprises a protein and is made up of amino acids. Group IV comprises an antibody to the protein, although antibodies themselves are proteins, they are different molecules with different structures. Though there may be overlap for these groups, the search for one group will not be coextensive with that of the other group.

Groups I and VII are drawn to methods and each is distinct from the other because they utilize different starting materials, therefore the outcomes are not be expected to be the same. Group I is drawn to a method for prostate cancer. Group V is drawn to a method of screening an inhibitor. Group VI is drawn to a method of using an inhibitor to treat prostate cancer. Group VII is drawn to a method of using transdominant mutants. Though there may be overlap

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between these two methods in question for groups I and V-VII, each utilizes different materials and therefore the outcome is expected to be different.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-746-3162.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ULRIKE WINKLER, PH.D.
PATENT EXAMINER 9/5/03